condition for further research. Improvement and selection inventions attenuate the resulting tensions between fundamental research and research targeted to specific applications. Combined with an intelligent use of cross-licenses, they represent an important means of balancing inventors' interests. Patent systems in the countries under consideration acknowledge this, and apply generally the same principles, often derived from chemical inventions.

Finally, the scope of protection issues arise in relation to *identified compounds.*[1190] Under both the German and the U.S. patent system, patents for manufacturing processes do not cover compounds obtained through screening. Therefore, the use of screened compounds does not establish infringement of patented screening processes. Under European statutes, a product must be obtained "directly" by means of the patented process to be covered by the patent. A product "directly" obtained from a patented process is the product with which the process ends. With regard to the subject under consideration, the *in-silico* screening operation is the manufacturing process. The question is thus whether identified compounds should be considered the direct result of this operation. The screening process, however, does not end with the identified compound, but with the database search. Thus, the use of identified compounds does not establish any infringement.

In the U.S., the *Bayer v. Housey* case demonstrated that the issue of identified compounds is treated in a similar fashion. The decision dealt with the question of whether the import of therapeutical compounds that were disclosed with the assistance of a patented process in a foreign country infringed the patented process as such under Section 271 (g) U.S.C. The reasoning of the court indicated that the term "made", as stated in the statue, must be understood as synonymous with "manufactured". Further, the patented screening process is not used in the actual design of the drug, because processes of identification and generation of data are not steps in the manufacture of a final drug product. For these reasons, the use of screened and imported compounds does not violate Section 271(g) as long as it is limited to the manufacture of physical goods and does not extend to knowledge that is generated by a patented process.[1191]

C. General Findings

New technologies always raise doubts about whether the patent system is suited for the fostering their advancement without creating excessive inefficiencies. From the preceding analysis, it should be clear that in the case of proteomics, traditional patent categories are often sufficient for coping with the challenges of the new technology. Thus, one of the more general results of this study is that proteomics as a subject matter of patent law should be considered as the continuation of classical protein research, which itself has assumed many legal concepts from the area of

1190 Chapter 4 C VII.
1191 Chapter 4 C VII 2.

chemical patents. These are combined with principles from other biotechnological fields and from the area of computer-implemented inventions to form the new set of principles that govern the IP treatment of the new technology.

The general set of rules and procedures that has developed during recent decades thus seems to be capable of adapting to the changing set of linguistic constructs that characterize modern scientific and economic processes. In fact, one of the most important yardsticks for a modern patent system seems to be whether it is flexible enough to deal with the very dynamic development of new research areas (in this study, genomics, post-genomics, proteomics, bioinformatics), each characterized by its own "language" of scientific communication. As shown in chapters III and IV, the application of existing principles does yield sensible solutions for dealing with issues of patentability and scope of protection in the area of proteomics.

Adequate principles, however, are only part of a successful application to a new technology. The study at hand also shows that the institutional framework of the patent system can and does react in a surprisingly flexible fashion to new types of inventions, and changes the way a scientific field is perceived. In the five years since the completion of the human genome project, the idea that one gene encodes one protein has been replaced by a dynamic view of cell physiology and biochemistry. Shortly thereafter, the focus of the resulting new field of proteomics itself changed markedly. It became clear that the 3-D structure of proteins is one of the major determinants of a protein's function, and perhaps the single most important one. Thus, within a very short period of time, the state of the art itself has experienced several structural breaks. As shown in chapter III, patent offices have quickly adapted to every new development, even in an anticipatory manner. Aided by the general principles that were laid down by legislative bodies and courts, they have succeeded in changing the focus whenever the biotechnological complex changed. It is worth noting that this flexibility was not hampered, but rather facilitated, by the existence of traditional patent categories.

With regard to proteomics, however, the patent system faces more serious and fundamental challenges than mere adoption to new linguistic constructs and to new research fields. Just as any invention that is likely to have spillover effects in terms of further innovation, the patentability of biotechnological compounds forces the patent system to strike a reasonable balance between open access and exclusivity. The tension between these two principles surfaces at various stages of this inquiry, a core topic of which is the multiple dimensions that determine the breadth and scope of a patent claim. Broad patents that cover a wide range of known and unknown protein characteristics and functions lead to *strong ex ante* incentives to invest in research and development. By contrast, narrow patents that preserve the incentives to explore spillovers and new aspects of a known compound are desirable *ex post*, as the economic benefits of newly discovered structural properties accrue to downstream inventors.[1192]

1192 The economic problems that arise due to conflicts between ex ante and ex post efficiency in the area of cumulative inventions (i.e., inventions that build upon each other) is extensively

This tension between *ex ante* and *ex post* optima dominates many debates in the area of IP protection in general, and biotechnological patents in particular.[1193] Did (broad) gene patents hinder further research? How did the patent system react when it became clear that knowledge about a protein's structure may prove to be much more important to the development of medical treatments than knowledge about the encoding gene, at least in the foreseeable future? How does it deal with the fact that scientific developments often lead to a change in perceptions as to what should be patented, and how broad the scope of a patent should be? Since it represents one of the major technologies in the post-genomic era, proteomics is a very good test case to answer these questions. Its study may deliver important insights into the mechanisms which the patent system provides and its flexibility in dealing with novel issues.

When dealing with issues of *ex post* and *ex ante* optimality, it should not be underestimated that governments faced with such fundamental trade-offs are in danger of suffering from problems of dynamic inconsistency.[1194] It would be socially optimal to credibly promise a strong and broad protection of IP rights (to encourage R&D investment, for example, to facilitate the identification of the genome) and to break this promise as soon as research has delivered the result (to facilitate and boost research on new technologies having more direct applications or a higher short-run success probability, like proteomics). The resulting credibility problem can only be solved by establishing a reputation for strong IP protection. At the same time, however, this emphasis on *ex ante* optimality has to be balanced with institutional mechanisms that provide enough flexibility to react to new technological developments and challenges.[1195]

From the analysis above, it seems that the patent system has developed intelligent solutions combining a broad scope of protection with flexible means of reducing the

disucssed in Scotchmer, Suzanne, Standing on the Shoulder of Giants: Cumulative Research and the Patent Law, Journal of Economic Perspective 1991, 29, and Scotchmer, Suzanne, Incentives to Innovate, In: The New Palgrave Dictionary of Economics and the Law; Newman, Peter, ed., McMillan: London, 1998; 273. See also Menell, Peter S., Intellectual Property: General Theories, In: Encyclopedia of Law and Economics, Volume II: Civil Law and Economics; Bouckaert, Boudewijn/De Geest, Gerrit Ed. Edward Elgar: Cheltenham, 1999; 129, who surveys the economic literature on patent law.

1193 Putnam, Jonathan D., The Price we Pay for Drug Research, Innovative Magazine 2004, 26, exemplifies this tension from a legal perspective, using the area of drug development and the trade-off between innovation and competition policy as examples.

1194 The fact that patent law is an area where the danger for dynamic inconsistency and "broken political promises" is especially large was already emphasized in the seminal contribution by Kydland, Finn E./Prescott, Edward C., Rules Rather than Discretion: The Inconsitency of Optimal Plans, 85 Jounal of Political Economy 1977, 473, for which the authors received the Memorial Nobel Prize in Economic Sciences in 2004.

1195 See also Putnam, Jonathan D., The Price we Pay for Drug Research, Innovative Magazine 2004, 26, for an applied treatment. A more formal economic reasoning with close relations to the subject of this thesis can be found in Craven, B. M./Fiala, C./Shiers, A./Steward, G. T., Time Consistency and the Development of Vaccines to treat HIV/Aids in Africa, 8 Economic Issues 2003, 15.

ex post cost of such solutions. For example, those observers who feared that gene patents may create monopoly positions, punishing the downstream inventors of the post-genomic era (i.e. , those who invent on the basis and around genetic information to deliver medical applications), should recognize that the existing institutional framework offers a number of mechanisms that attenuate such problems. Besides the use of cross-licensing, the practice of granting research exemptions, though still hotly debated in the U.S., offers a relatively new but effective means for guaranteeing the free flow of scientific information and the advancement of fundamental research. Moreover, the concept of "non-obviousness", "inventive step" or "Erfindungshöhe" impedes excessively aggressive patenting strategies by limiting patentability to research efforts that provide a significant benefit to society. In the genomic era, this was exemplified when the widespread patenting of ESTs was prevented. In the proteomic era, a number of bioinformatics inventions are already under close scrutiny as to whether they are obvious.

Recapitulating, those who criticize intellectual-property-right protection from an economic perspective, argue that "it has become increasingly clear that excessively strong or poorly formulated intellectual property rights may actually impede innovation". In particular, they claim that "sorting out the relative contribution [of different ideas] to the outcome … can be nearly impossible".[1196] However, these critics should recognize that the patent system has developed a number of principles that are capable of balancing the interest of multiple parties without having to define the exact contribution of single participants in the scientific process. Since its establishment, the patent system's primary occupation has been to deal with innovations. It is therefore not surprising that the legal principles that have developed over a long period of time are an adequate means for protecting current innovators without hampering innovators in fields that have yet to be defined and explored. In this respect, the field of proteomics, though still in its early stages, is an inspiring example.

1196 Stiglitz, Joseph E., Intellectual-property rights and wrongs, Daily Times (Pakistan) 2005.